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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,246	07/24/2003	Christopher J. Elliott	10123/00601	1009

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Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER

HOUSTON, ELIZABETH

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,246	ELLIOTT, CHRISTOPHER J.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 13-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>010305</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-12 and 24-26, drawn to apparatus, classified in class 606, subclass 200.
 - II. Claims 13-23, drawn to method of making, classified in class 29, subclass 447.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made with a materially different process such as one that involves using a first and second mandrel for shaping the coil.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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5. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Patrick Fay on 08/25/06 a provisional election was made without traverse to prosecute the invention of apparatus, claims 1-12 and 24-26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "*elongated outer element comprises a platinum wire co-wound with a wire formed of shape memory material*" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 6-10, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Kupiecki (USPN 5,980,514).

10. Kupiecki discloses an embolic coil comprising an elongated core element (Fig 8, 204) formed of a shape memory material, nitinol, (Col 14, line 16) treated to define a memorized secondary coil shape; and an elongated outer element (202) wound around the elongated core element to define a primary coil shape of the embolic coil and formed of platinum (Col 14, line 18). It is inherent that the shape memory material, of which the elongated core element is formed, is in an austenitic phase at an operation temperature of the embolic coil. The secondary coil has a secondary coil memorized

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shape, wherein, when heated to a temperature above a critical temperature of the shape memory material, the secondary coil causes the primary coil to follow the secondary coil shape (Col 14, lines 33-35).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 3, 4, 11 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki in view of Villar (USPN 6,287,318).

13. Kupiecki discloses all the limitations of the instant invention substantially as claimed as stated above except for the coil has fibers.

14. Villar discloses an embolic coil comprising polymeric fibers, which promote tissue growth by facilitating the formation of scar tissue, healing tissue or neocapillaries in vascular occlusions.

15. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the fibers into the coil since they enhance the performance of the coil as stated by Villar. The inventions are analogous with each other and the instant invention and therefore the combination is proper.

16. Regarding claim 11, Kupiecki in view of Villar discloses the invention substantially as claimed as stated above. However Kupiecki in view of Villar fails to

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disclose fiber retention grooves. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the embolic coil. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki.

1. Kupiecki discloses the invention substantially as claimed as stated above. However Kupiecki fails to disclose the elongated outer element comprises a platinum wire co-wound with a wire formed of a shape-memory material. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected result to the embolic coil. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

18. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki.

19. Kupiecki teaches an outer elongated element with a primary coil shape but is silent as to how the primary shape is formed. The claimed phrase "cold working" is being treated as a Product by Process limitation that is the primary shape of the outer elongated element is formed by cold working. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a

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product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP § 2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

20. Thus, even though Kupiecki is silent to the process used to form the cut, it appears that the product disclosed by Kupiecki would be the same or similar as that claimed; especially since both applicant's product and the prior art product has an embolic coil with a core and an outer element and a primary and secondary shape.

ALTERNATIVELY:

21. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kupiecki in view of Ferrera (USPN 6,171,326).

22. Kupiecki discloses all the limitations of the instant invention substantially as claimed as stated above except for applying cold work to the outer element.

23. Ferrera teaches cold working as a way of shaping embolic coils (Col 3, line 63-64).

24. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the use of cold working since it is a known process in the art as disclosed by Ferrera. The inventions are analogous with each other and the instant invention and therefore the combination is proper. Therefore, even if "cold working" results in different structural characteristics of the end product than other methods, it still

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would have been *prima facie* obvious at the time the invention was made to use "cold working" in Kupiecki as claimed since Ferrera teaches that "cold working" is recognized as a useful technique for forming embolic coil shapes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh



ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER



2/2/06